DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

MAY - 8 2003

2757 '03 MAY 28 P2:34

Mr. Rich Razgaitis
President
Blaine Pharmaceuticals
1515 Production Drive
Burlington, Kentucky 41005

Dear Mr. Razgaitis:

This is in response to your letter of April 25, 2003 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(5) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Blaine Pharmaceuticals is making the following claims for the product **MAG-OX-400®**:

> "For a wide variety of patients at risk for magnesium depletion, including diabetics, pregnant women, migraine sufferers, hypertensive patients, and cardiac patients, the importance of magnesium supplementation is becoming increasingly apparent;"
>
> "Hypomagnesmia itself may contribute to high blood pressure and cardiac dysrhythmia."

21 U.S.C. 343(r)(6)(A) provides, among other things, that the labeling of a dietary supplement may bear a statement that "claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States." Such a statement may be made if the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, the statement contains the disclaimer statement specified by the statute, the manufacturer submits the required notification no later than 30 days after the first marketing of the dietary supplement, and the statement does not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases.

The statement "Hypomagnesmia itself may contribute to high blood pressure and cardiac dysrhythmia) is a statement that describes a consequence of magnesium deficiency (i.e., hypomagnesmia) that appears to misbrand the product under 21 U.S.C. 343(r)(6)(A) because it describes a benefit related to a classical nutrient deficiency disease but does not disclose the prevalence of the subject deficiency disease in the United States. Moreover, some of the statements about these products appear to misbrand the products under 21 U.S.C. 343(a)(1) in that they are false and misleading because they imply that magnesium deficiency or depletion is a consequence of various diseases and/or their treatment and we are unaware of any evidence to conclude that such statements are supported by substantiation that they are truthful and not misleading.

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21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. 21 U.S.C. 321(g)(1) (last sentence) provides that a food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) (i.e., 21 U.S.C. 321(g)(1)(C)) solely because the label or the labeling contains such a statement. In that the statements being made for the product MAG-OX-400 are not made in accordance with 21 U.S.C. 343(r)(6), they suggest that the product is intended to treat, prevent, mitigate, or cure diseases or is an article (other than food) intended to affect the structure or any function of the body of man. These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B) and (C), and that it is subject to regulation under the drug provisions of the Act.

Please contact us if we may be of further assistance.

Sincerely yours,

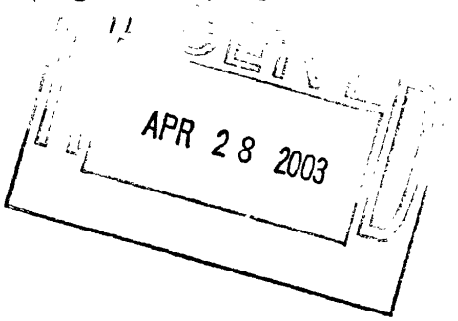
Susan J. Walker, M.D.
Acting Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Cincinnati District Office, Office of Compliance, HFR-MA440

BLAINE Pharmaceuticals
1515 Production Drive, Burlington, Ky 41005
p.859.283.9437 1.800.633.9353 f.859.283.9460 www.blainepharma.com

April 25, 2003

VIA FACSIMILE (301) 436-2639
(Original Sent By Regular Mail)



Food and Drug Administration
Dietary Supplement Branch
Office of Nutritional Products, Labeling and Dietary Supplements
HFS-810
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, Maryland 20140

Dear Sir/Madam:

In accordance with 21 CFR §101.93(a), Blaine Pharmaceuticals, Inc., 1515 Production Drive, Burlington, KY 41005, provides notice to the Food and Drug Administration of the marketing of a dietary supplement bearing the following statements in the labeling:

Statements: For a wide variety of patients at risk for magnesium depletion, including diabetics, pregnant women, migraine sufferers, hypertensive patients, and cardiac patients, the importance of magnesium supplementation is becoming increasingly apparent.

Hypomagnesmia itself may contribute to high blood pressure and cardiac dysrhythmia.

So patients can feel confident it's working – like an ox – to give them the magnesium they need to stay strong and healthy.

Subject of Claims: Magnesium Oxide, USP

Name of Supplement: MAG-OX-400®

The information contained in this notice is complete and accurate. The files of Blaine Pharmaceuticals contain substantiation that the statements made are truthful and not misleading.

Should you have any questions pertaining to this notification, please contact me at (859) 372-8080 Ext. 17.

Sincerely,

Rich Razgaitis
President